



Get projects done.



Kymanox Commissioning and Validation Services

Your Commissioning and Validation Needs

Kymanox caters to your **specific needs** to get commissioning and validation done. Key subject areas include process, cleaning, facilities, clean utilities, equipment, computer systems, and environmental chambers.

- **Scope, timelines, and budgets** are actively managed to meet your requirements
- Expertise in factory-based qualifications support **compressed start-up schedules**
- Extensive **design experience** facilitates required technical understanding
- A designated **Technical Project Manager** is assigned to your project

Your Regulatory Requirements

Kymanox knows how to comply with the regulations issued by governmental agencies (e.g., FDA, EMEA, etc.) and how to make the most of industry guidance issued by both governmental and non-governmental bodies (e.g., ISPE, ISO, etc.):

- Kymanox knows what **regulations** apply to you
- Kymanox understands how to **interpret** the regulations and available guidance
- Experienced in **Biotechnology, Pharmaceuticals, and Medical Devices**

Expertise for Your Project

Kymanox ensures that the best, **multi-disciplinary team** is available for your project:

- Professional Project Management
- Chemical Engineering
- Process Engineering
- Biomedical Engineering
- Mechanical Engineering
- Electrical Engineering
- Automation & Computer Systems
- Quality & Regulatory
- Professional Engineering (PE)
- GMP Statistics

Your Documentation

Kymanox knows that **documentation is everything** and is as important as the quality of executed work. Kymanox has experience authoring the following documents:

- User Requirements (URS)
- Functional Requirements (FRS)
- Detail Design Documents
- Turnover Packages (TOP)
- Commissioning Protocols
- Engineering Studies
- Standard Operating Procedures
- Factory and Site Testing (FAT/SAT)
- Work Instructions / Batch Records
- Validation Protocols (IQ/OQ/PQ)
- Final Reports
- Maintenance Procedures

Contact Kymanox

US Toll Free (866) 497-7931 | Outside US +001 919-246-4896 | info@kymanox.com | www.kymanox.com